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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,376	07/28/2001	Shi-You Ding	NREL 01-36	9956

7590 05/18/2007

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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1652	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/917,376	DING ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-9,12,14,15,28,30-36,43,48 and 50-59* is/are pending in the application.

4a) Of the above claim(s) *8 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7,9,12,14,15,28,30-36,43,48,50-57 and 59* is/are rejected.

7)☒ Claim(s) *4,5,7,8,28,50,51,53,54 and 59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

The approval of Applicants' petition to revive, granted March 29, 2007, is acknowledged.

Applicant's Request for Continuing Examination and response of December 8, 2006 are acknowledged. It is acknowledged that Claims 6 and 49 have been cancelled, Claims 1, 2, 12, 28, 31, 48, 50-56 have been amended, and Claims 57-59 have been added. Claims 57-59 are encompassed within the elected invention, which is directed to the AviIII protein of SEQ ID NO: 1 comprising the catalytic domain of SEQ ID NO: 3 and the carbohydrate binding domain of SEQ ID NO: 4 (response of March 19, 2004). Claims 1, 2, 4, 5, 7-9, 12, 14, 15, 28, 30-36, 43, 48, 50-59 are pending. Claim 8 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 1, 2, 4, 5, 7, 9, 12, 14, 15, 28, 30-36, 43, 47, 48, 50-57, and 59 are hereby examined.

Priority

The priority date granted for the instant invention is July 28, 2001, the filing date of the instant application.

Specification-Objections

The specification is objected to for disclosing sequences, for example in Table 5 as filed February 8, 2006, that are not identified by a sequence identifier number (SEQ ID NO:). The sequence rules embrace all nucleotide sequences with ten or more bases and all amino acid

sequences with four or more amino acids. Said sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02). 37 CFR 1.821(d) requires the use of the assigned sequence identifier number in all instances where the description or claims of a patent application discuss sequences, regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is required to check the disclosure completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

Claims-Objections

Claims 4, 5, 7, 8, and 53 are objected to for "carbohydrate binding domain (CBD) III", which is first defined in Claim 2. Repetition of the definition is unnecessary.

Claims 28, 50, 53, 54, and 59 are objected to for "glycosyl hydrolase family 74 (GH74 Ace)", which is first defined in Claim 2. Repetition of the definition is unnecessary.

Claim 50 is objected to for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:). Claim 51, as dependent from Claim 50, is objected to for the same reasons.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 7, 9, 12, 14, 15, 28, 30-36, 43, 48, 50-57, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Claims 1, 28, 50, 52, 53, 55-57, and 59 are rendered indefinite by the phrase "A composition comprising a genetically engineered polypeptide expressed in a heterologous cell". It is unclear whether said composition comprises the protein within the heterologous cell or free of the heterologous cell. The skilled artisan would not know the metes and bounds of the recited invention. Claims 2, 4, 5, 7, 9, 14, 15, 30-36, 43, 48, 51, and 54, as dependent from one or more of Claims 1 28, 50, and 53, indefinite for the same reason. For purposes of examination, it is assumed that the composition comprises the protein free of the heterologous cell.

Claim 12 is rendered indefinite by the phrase "A genetically engineered polypeptide expressed in a heterologous cell". It is unclear whether said phrase comprises the protein only within the heterologous cell or also free of the heterologous cell. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that the phrase encompasses the protein within the heterologous cell and also free of the heterologous cell.

For Claim 28 and 50, the phrase "...having catalytic activity of a glycosyl hydrolase family 74 (GH74 Ace) enzyme" renders the claims indefinite. Neither the claims, nor the specification, define said glycosyl hydrolase family 74 (GH74 Ace) enzyme activity. Likewise, for Claim 50, the phrase "comprising a catalytic domain a glycosyl hydrolase family 74 (GH74 Ace) enzyme" and for Claim 59, the phrase "providing cellulase activity as a glycosyl hydrolase family 74 (GH74 Ace) enzyme" renders the claims indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claims 30-36, 43, and 51, as dependent from Claim 28 or 50, are indefinite for the same reason.

Claim 43 is rendered indefinite by the phrase "A composition". It is unclear whether said claim further limits the composition of Claim 28, from which it depends, or is meant to recite an independent composition.

For Claims 48 and 51, the term "retains" renders the claim indefinite. It is unclear under what conditions the retention of activity is measured or what specific characteristics of the enzyme are retained.

Claim 51 is rendered indefinite by being dependent from a cancelled claim. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that Claim 51 is dependent from Claim 50.

For Claim 53, the term "characterized by" renders the claim indefinite. It is unclear whether said term means "has", "similar to" or some other meaning. The skilled artisan would not know the metes and bounds of the recited invention.

For Claim 59, the phrase "means for providing cellulase activity as a glycosyl hydrolase 74 (GH74) family enzyme according to SEQ ID NO: 1" renders the claim indefinite for two reasons. First, it is unclear "means for providing" means; does it mean that the protease has the activity? Second, it is unclear as to whether "as a glycosyl hydrolase 74 (GH74) family enzyme according to SEQ ID NO: 1" means that the recited polypeptide has the same activity as the polypeptide of SEQ ID NO: 1. The skilled artisan would not know the metes and bounds of the recited invention.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 2, 4, 5, 7, 9, 12, 14, 15, 28, 30-36, 43, 48, 50-57 and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 1, does not reasonably provide enablement for any variant of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1, 2, 4, 5, 7-9, 12, 14, 15, 28, 30-36, 43, 48, 50, and 51 are so broad as to encompass any cellulase polypeptide having at least 90% identity to SEQ ID NO: 1. Claim 52 is so broad as to encompass any polypeptide, having any or no activity, and comprising any fragment of SEQ ID NO: 1. Claim 53 is so broad as to encompass any polypeptide, having any or no activity, and comprising any carbohydrate binding domain III and any hydrolase domain having at least 90% identity with SEQ ID NO: 3. Claims 54 is so broad as to encompass any polypeptide, having any or no activity, and comprising any carbohydrate binding domain III and the hydrolase domain of SEQ ID NO: 3. Claim 55 is so broad as to encompass any polypeptide, having any or no activity, and having at least 90% identity with SEQ ID NO: 1. Claim 56 is so broad as to encompass any polypeptide, having any or no activity, and having at least 90% identity with SEQ ID NO: 3. Claim 57 is so broad as to encompass any polypeptide, having at least 90% identity with SEQ ID NO: 4 and having carbohydrate binding activity. Claim 59 is so broad as to encompass a polypeptide with any structure and having hydrolase activity. Claim 30 is so broad as to further comprise a heterologous peptide that can bind to any carbohydrate polymer. Claim 34 is so broad as to further comprise a heterologous peptide that can promote oligomerization. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in

which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques as well has hydrolase assays are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1, 2, 4, 5, 7-9, 12, 14, 15, 28, 30-36, 43, 48, 50, and 51, which encompasses any polypeptide having at least 90% homology to SEQ ID NO: 3 and having cellulase activity. The specification does not support the broad scope of Claims 52-56, which encompasses any polypeptide having any or no activity and having any fragment of SEQ ID NO: 1, any CBD III domain, at least 90% homology to SEQ ID NO: 3, and/or at least 90% homology with SEQ ID NO: 1. The specification does not support the broad scope of Claim 57, which encompasses any polypeptide having at least 90% identity with SEQ ID NO: 4 and having carbohydrate binding activity. The specification does not support the broad scope of Claim 59, which encompasses any polypeptide with any structure and having hydrolase activity. The specification does not support the broad scope of Claims 1, 2, 4, 5, 7, 9, 12, 14, 15, 28, 30-36, 43, 48, 50-57 and 59 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting the desired activity;

(B) the general tolerance of the desired activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of proteins with an enormous number of amino acid modifications of the polypeptide of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Rejection of Claims 50 and 51 under 35 U.S.C. 112, first paragraph/written description, because the original specification and claims fail to disclose the limitation of "identical to SEQ ID NO: 3 in each conserved position marked by an asterisk (*), as shown below in comparison to *Aspergillus aculeatus* Avicelase III(AviIII_Aac)", as recited in Claims 50 and 51, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that Table 5 on page 37 of the original specification show the sequence comparison between GH74_Ace and AviIII_Aac and that page 36 contains an explanation of the asterisk *. This argument is not found to be persuasive for the following reasons. The original specification, filed July 28, 2001,

is only 35 pages long and does not contain a Table 5. It is assumed that Applicants are referring to original Table 3 on page 34. It is acknowledged that said table, and the discussions thereof, teach that the polypeptide of GH74_Ace has residues in common with AviIII_Aac. However, said teachings are not a disclosure of polypeptides having at least 90% homology to SEQ ID NO: 1 and having a sequence identical to SEQ ID NO: 3 in each position marked with an asterisk *. The original disclosure fails to teach said polypeptides. Therefore, the limitation "having a sequence identical to SEQ ID NO: 3 in each position marked with an asterisk *" in Claims 50, introduces New Matter. Therefore, Rejection of Claims 50 and 51 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior action and above, is maintained.

Claims 1, 2, 4, 5, 7-9, 12, 14, 15, 28, 30-36, 43, 48, 50, and 51, 57, and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of proteins having one or more of the following characteristics (i) any cellulase polypeptide having at least 90% identity to SEQ ID NO: 1 (ii) any polypeptide, having at least 90% identity with SEQ ID NO: 4 and having carbohydrate binding activity, (iii) any polypeptide with any structure and having hydrolase activity, (iv) additionally comprising any heterologous peptide that can bind to any carbohydrate polymer, or (v) additionally comprising any heterologous peptide that can promote oligomerization. The specification teaches the structure of only a single representative species of such proteins. Moreover, the specification fails to describe any other representative species by any identifying characteristics

or properties other than the functionality of having cellulase activity, carbohydrate binding activity, or oligomerization activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of proteins having one or more of the following characteristics (i) comprising any fragment of SEQ ID NO: 1, (ii) comprising any carbohydrate binding domain III and any hydrolase domain having at least 90% identity with SEQ ID NO: 3, (iii) comprising any carbohydrate binding domain III and the hydrolase domain of SEQ ID NO: 3, (iv) having at least 90% identity with SEQ ID NO: 1, or (v) having at least 90% identity with SEQ ID NO: 3. The specification does not contain any disclosure of the function of all said proteins. The genus of polypeptides that comprise these above protein molecules is a large variable genus with the potentiality of having many different activities. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims, including proteins with no activity. The specification discloses the function of only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 52 is rejected under 35 U.S.C. 102(b) as being anticipated by Seeger et al, 1999. Claim 52, comprises the phrase "an amino acid sequence identical to SEQ ID NO: 1". Said phrase encompasses any fragment of SEQ ID NO: 1, including peptides as small as two residues. Seeger et al teach a composition comprising a polypeptide, wherein the polypeptide comprises residues 472-481 of SEQ ID NO: 1 (see enclosed alignment). Therefore, Claim 52 is rejected under 35 U.S.C. 102(b) as being anticipated by Seeger et al, 1999.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1652